Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class: **Synagis® (palivizumab)**
Prepared for: Missouri Medicaid
Prepared by: Missouri Medicaid

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose: Promote prudent prescribing of Synagis® (palivizumab).

Why was this Issue Selected: Recently, the American Academy of Pediatrics (AAP) published newly updated guidelines for the use of palivizumab. Only pediatric patients at high risk for RSV infection require prophylaxis with this agent. Because the associated costs of palivizumab may be as high as $5,000 per patient per season, prudent prescribing of this agent is imperative.

Program-specific information:

Drug	Claims	Expense
• Synagis® (palivizumab)	*3729*	*$4.4 million*

Setting & Population: All individuals prescribed palivizumab.

Type of Criteria:
☐ **Increased risk of ADE**
☐ **Non-Preferred Agent**
☒ **Appropriate Indications**
☐ **Dose Optimization**

Data Sources:
☐ **Only administrative databases**
☒ **Databases + Prescriber-supplied**

Purpose of Clinical Edit

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical Edit criteria, which is different from prior authorization or prior approval programs, assist in the achievement of qualitative and economic goals related to health care resource utilization without placing the entire utilization of a drug in a PA status. Screening the use of certain medications on the basis of clinical appropriateness can reduce costs by requiring evidence of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical Edit criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Why Has This Clinical Issue Been Selected For Review?

In the United States, respiratory syncytial virus (RSV) infection accounts for more than 90,000 pediatric hospitalizations and 4,500 deaths annually.[1] Symptoms of RSV are usually self-limiting in those individuals that are considered healthy and have normally developed respiratory systems. However, the risk of serious RSV illness is highest among pediatric patients with specific risk factors (i.e., prematurity, chronic lung disease, congenital heart disease, multiple congenital anomalies, and certain immunodeficiencies).[2] When RespiGam® (RSV-IGIV), the human immunoglobulin for RSV, was approved in 1996 for the prevention of RSV, it provided a much needed benefit for infants by preventing hospitalizations associated with RSV. However, RSV-IGIV has many disadvantages. It must be given by slow IV infusion, its supply is limited by lack of donors, and a child's immunizations must be carefully scheduled surrounding its administration.[4] Synagis® (palivizumab), is a humanized monoclonal antibody (IgGIk) produced by recombinant DNA technology that binds to the F glycoprotein of RSV.[3] It was approved for marketing by FDA in June 1998 and addresses the administration and safety concerns noted with RSV-IGIV.[4]

RSV prophylaxis with palivizumab for two RSV seasons for those patients with less severe underlying disease is generally not recommended and should only be reserved for those patients with more severe chronic lung disease (i.e., those requiring medical therapy).

Palivizumab is dosed at 15 mg/kg every 28 days during the RSV season. While costs of a single 100 mg vial approximates $1400, total cost for treatment may exceed $5,000 per patient per season, therefore prior authorization is imperative to promote prudent prescribing of this agent.[5]

Approval Criteria

- **Drug for review:** **Synagis® (palivizumab)**
- **Age range:** **Age < 2**

Approval Criteria	
Treatment is being administered at the start or within the RSV season (based on geographical area).	Approved
< 2 years old with chronic lung disease that required treatment in the past 6 months.	Approved
Patients born ≤28 weeks of gestation* and are currently ≤1 year of age.	Approved
Patients born between 29 and 32 weeks gestation* and are currently ≤6 months of age.	Approved
Patients born between 32 and 35 weeks gestation *and are currently ≤6 months of age if they have two or more multiple risk factors present such as: • Child care attendance • School-aged siblings • Exposure to environmental air pollutants • Congenital abnormalitites of the airways • Severe neuromuscular disease • Low birth weight • Long distance from hospital care *Weeks gestation calculated by completed weeks of gestation.	Approved
≤24 months of age with hemodynamically significant cyanotic and acyanotic congenital heart disease.	Approved
Infants younger than 12 months of age with congenital heart disease who most likely are to benefit from immunoprophylaxis such as: • Those receiving medication to control CHF • Those with moderate to severe pulmonary hypertension • Those with cyanotic heart disease	Approved
Children with severe immunodeficiencies who may benefit from prophylaxis. (Subject to clinical/medical review)	Approve

Denial Criteria

- Infants not meeting approval criteria.
- Infants and children with hemodynamically insignificant heart disease including:
    - Secundum atrial septal defect
    - Small ventricular septal defect
    - Pulmonic stenosis
    - Uncomplicated aortic stenosis
    - Mild coarctation of the aorta
    - Patent ductus arteriosus
- Infants with lesions adequately corrected by surgery unless they continue to require medication for CHF.
- Infants with mild cardiomyopathy who are not receiving medical therapy.

Required Documentation

Laboratory results:	☐	Progress notes:	☐
MedWatch form:	☐	Other:	☐

References

1. Institute of Medicine Committee on Issues and Priorities for New Vaccine Development. Prospects for immunizing against respiratory syncytial virus. In: New Vaccine Development, Establishing Priorities. Washington, DC: National Academy of Sciences Press;1988;1:397-409.Synagis.
2. The IMpact-RSV Study Group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. *Pediatrics.* 1998;102:531-537.
3. Palivizumab for intramuscular administration. Gathersburg, MD: MedImmune, Inc; 12/99. Package Insert.
4. Nahata M,Robinson R. Respiratory syncytial virus (RSV) immune globulin and palivizumab for prevention of RSV infection. *Am J Health-Sys Pharm* 2000;(57):259-264.
5. Drug Topics Red Book 2002. Thomson Medical Economics. Synagis.
6. American Academy of Pediatrics Committee on ID and Comm on Fetus and Newborn-Prevention of RSV Infections: Indications for the use of palivizumab and update on the use of RSV-IGIV. *Pediatrics* 1998;102(5):1211-1215.
7. RSV Guidelines Evaluation-A Comparison Study. Mark Roaseau, BS Pharmacy, MD. July 2003.